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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO | CONFIRMATION NO |
|-----------------------------------------------------------------------------------------------------------|-------------|----------------------|------------------------|-------------------------------------------------------|
| 09 762,131 | 01 31 2001 | Toshihiko Yamauchi | TOYAM69.001A | 8649 |
| 20995 | 7590 | 03 12 2002 | | |
| KNOBBE MARLENS OLSON & BEAR LLP 620 NEWPORT CENTER DRIVE SIXTEENTH FLOOR NEWPORT BEACH, CA 92660 | | | EXAMINER [REDACTED] | GAMBEL, PHILLIP |
| | | | ART UNIT 1644 | PAPER NUMBER [REDACTED] DATE MAILED: 03 12 2002 |

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| | | |
|--------------------|------------------|--|
| Application No. | Applicant(s) | |
| 09/762131 | YAMAMUCHI OTAKU | |
| Examiner GAMBEL | Art Unit 1644 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 1/31/01
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.
- 4) Claim(s) 1-6 is/are pending in the application
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 - 5) Claim(s) _____ is/are allowed.
 - 6) Claim(s) _____ is/are rejected.
 - 7) Claim(s) _____ is/are objected to.
 - 8) Claim(s) 1-6 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 1/31/01 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

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Serial No. 09/762131
Art Unit 1644

DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Technology Center 1600.
2. Applicant's amendment, filed 1/31/01 (Paper No. 3), has been entered.
Claims 3-5 have been entered.

Claims 1-5 are pending.
3. No Information Disclosure Statement has been provided in this application.
4. Formal drawings, filed 1/31/01, comply with CFR 1.84.
5. Prior to setting forth the restriction requirement, it is pointed out that the claims rely upon patentably distinct products. The method and products rely upon gp39 antagonists (page 5 of the instant specification), including anti-gp39 antibodies, soluble CD40 and soluble CD40L which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species.
6. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.
 - I. Claims 1-2, drawn to an agent which is an anti-gp39 antibody.
 - II. Claim 1, drawn to an agent which is soluble CD40.
 - III. Claim 1, drawn to an agent which is soluble gp39.
 - IV. Claims 3-5, drawn to methods of preventing ITP with anti-gp39 antibodies.
 - V. Claims 3 and 5, drawn to methods of preventing ITP with soluble CD40.
 - VI. Claims 3 and 5, drawn to methods of preventing ITP with soluble gp39.

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7. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Kalled et al. (WO 98/39026) (cited on 210 Search Report). Kalled et al. teach therapeutic anti-CD40L (i.e. anti-gp39) antibodies, including recombinant antibodies and fragments thereof (see entire document, including pages 6-8). The claimed functional limitations of preventing ITP would be an inherent properties of the referenced CD40L-specific antibodies. A composition is a composition irrespective of what its intended use is.

Accordingly, Groups I-VI are not so linked by the same or a corresponding special technical feature as a contribution over the prior art to form a single general inventive concept.

8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gabel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gabel

Phillip Gabel, PhD.
Primary Examiner
Technology Center 1600
March 11, 2002